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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/567,426

05/16/2006

Werner Lubitz

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8425

6449 7590 03/12/2007  
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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
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3 MONTHS

03/12/2007

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/12/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/567,426	LUBITZ, WERNER	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6February2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/6/06</u> . | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

1. Applicant's Preliminary Amendment, received 6 February 2006, is acknowledged. Claims 4, 7, 8, 9, 11, 12, 14, 16, 17, 18, and 19 have been amended.
2. Claims 1-19 are pending and under consideration.

### **Specification**

3. The disclosure is objected to because of the following informalities:

Page 1, line 1, the title "Closure of ....." does not match the title on the rest of the application forms, i.e., "Sealing....."

Page 11, line 25, there appears to be an asterisk immediately following "obtained".

Page 13, line 19, "figure 4B" should be "Figure 4B".

Page 14, line 12, "figure 1B" should be "Figure 1B", line 16, "figures 1C" should be "Figures 1C"; line 19, "figure 1E" should be "Figure 1E"; line 25, "figure 1F" should be "Figure 1F".

Page 17, line 13, "figure 2" should be "Figure 2", line 24, "figure 3" should be "Figure 3"; line 27, "figure 4A" should be "Figure 4A".

Page 18, line 12, "figure 5" should be "Figure 5"; line 21, "figure 6" should be "Figure 6".

Appropriate correction is required.

### **Drawings**

4. Figures 5 and 6 are objected to under 37 CFR 1.83(a) because they fail to show the cell details and arrows as described in the specification. The Figures are too indistinct to determine any structures.

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Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

#### **Claim Rejections - 35 USC § 101**

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 17-19 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See

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for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### **Claim Rejections - 35 USC § 112**

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "the fusion" is mediated by binding pairs. It is unclear which interaction is being considered "the fusion", i.e., the contact of the carrier materials to the ghosts, or the actual closure of the ghosts. The indefiniteness is compounded by dependent claim 11 which recites that the method "furthermore" comprises an at least partial fusion of the membrane of the ghosts and the carrier membranes. Thus, it is unclear what is encompassed by the term "the fusion". Claims 2-19 depend from claim 1, but do not clarify the issue.

9. Claims 17-19 provide for the use of closed bacterial ghosts in medicine, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

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10. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The wording of the Markush group is unclear. For example, is the biotin by itself or paired with streptavidin. If not, then it is suggested that each of the binding pairs be listed separately, i.e., the group consisting of: biotin/streptavidin, biotin/avidin, biotin analogues/streptavidin, biotin analogues/avidin, hapten/antibodies, hapten/antibody fragments, saccharide/lectin, and ligand/receptor.

11. Claims 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Both claims recite that the ghosts are "derived from" bacteria. The term "derived from" is unclear in its metes and bounds.

12. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The list active compounds lists as one of its components the term "substances". It is unclear what are the metes and bounds of this term.

13. Claims 17-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method of making closed bacterial ghosts utilizing bioaffinity binding pairs, does not reasonably provide enablement for "use" of said ghosts in the fields of medicine, agriculture, and biotechnology. The specification does not enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention -"use" of said closed bacterial ghosts in the fields of medicine, agriculture, and biotechnology.

The state of the prior art concerning closed bacterial ghosts for drug/activated ingredients delivery is known (DE19907770 A, Lubitz, 2000, cited in the specification). However, because the claims do not recite any actual steps on how the closed bacterial ghosts are to be utilized in medicine, agriculture, or biotechnology, there is a lack of predictability in the art concerning the unknown scope of the claims.

The amount of direction or guidance present in the specification is insufficient support for the scope of the claims because the only examples are directed to the production of the closed bacterial ghosts, and there are no examples of their utilization in the fields of medicine, agriculture, or biotechnology.

Therefore, the instant claims constitute merely an invitation to experiment without a reasonable expectation of success because the claims do not define the scope of the claimed inventions.

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### Conclusion

14. No claims are allowed.
15. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571)272-0787.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

March 3, 2007